

Guidance

Patents if there's no Brexit deal

Published 24 September 2018

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A scenario in which the UK leaves the EU without agreement (a 'no deal' scenario) remains unlikely given the mutual interests of the UK and the EU in securing a negotiated outcome.

Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal. However, it's our duty as a responsible government to prepare for all eventualities, including 'no deal', until we can be certain of the outcome of those negotiations.

For two years, the government has been implementing a significant programme of work to ensure the UK will be ready from day 1 in all scenarios, including a potential 'no deal' outcome in March 2019.

It has always been the case that as we get nearer to March 2019, preparations for a no deal scenario would have to be accelerated. Such an acceleration does not reflect an increased

likelihood of a 'no deal' outcome. Rather it is about ensuring our plans are in place in the unlikely scenario that they need to be relied upon.

This series of technical notices sets out information to allow businesses and citizens to understand what they would need to do in a 'no deal' scenario, so they can make informed plans and preparations.

This guidance is part of that series.

Also included is an <u>overarching framing notice</u> explaining the government's overarching approach to preparing the UK for this outcome in order to minimise disruption and ensure a smooth and orderly exit in all scenarios.

We are working with the devolved administrations on technical notices and we will continue to do so as plans develop.

Purpose

If the UK leaves the EU in March 2019 without a deal, find out in this notice how this would affect:

- the UK patent system and supplementary protection certificates
- the Unified Patent Court and unitary patent
- correspondence addresses and confidentiality for UK patents

Patents and supplementary protection certificates

Before 29 March 2019

Only a few areas of UK patent law come from EU legislation (supported by, or implemented via, UK domestic legislation such as the Patents Act 1977). One important area relates to patented pharmaceutical products and agrochemicals where EU law provides for an additional period of protection after a patent has run out. This is called a supplementary protection certificate.

Additionally EU law:

- sets out legal provisions on the patenting of biotechnological inventions. This includes exceptions from patenting, the scope of any protection, and a compulsory licensing regime between overlapping patents and plant variety rights
- provides processes for a compulsory licence to be granted for UK manufacture of a patented medicine for export to a country with a public health need
- sets out an exception that certain studies, trials and tests can be carried out using a patented pharmaceutical product without there being an infringement of the patent

A broader exception to infringement is also set out in UK law which allows for other activities to be carried out to meet regulatory requirements for medicines. This exception relies on references to relevant EU law.

After March 2019 if there's no deal

The relevant EU legislation (or its domestic implementation) will be retained in UK law under the EU Withdrawal Act 2018.

The existing systems will therefore remain in place, operating independently from the EU regime, with all the current conditions and requirements.

Any UK legislation supporting the existing systems will also continue to function as normal.

This means that the EU's legislation on supplementary protection certificates will be kept in UK law. This law, along with the existing supporting provisions in UK patents legislation, will form the UK's own supplementary protection certificate regime on exit.

Likewise, all other EU legislation relevant to patents and supplementary protection certificates will be kept in UK law. This will ensure UK law continues to work in respect of biotechnology patents and applications, compulsory licensing arrangements, and exceptions from infringement for the testing of pharmaceutical products. Issues relating to the unitary patent are covered elsewhere in this notice.

Implications

Any existing rights and licences in force in the UK will remain in force after March 2019. For UK, EU and third country businesses there will be no significant change to the legal requirements or the application processes. In particular, pending applications for patents and for supplementary protection certificates will continue to be assessed on the same basis, and new applications can continue to be filed. If legal proceedings involving these rights or licences are underway, they will continue unaffected.

The supplementary protection certificate regime in the UK will continue to operate as before for UK, EU and third country businesses.

The conditions for patenting biotechnological inventions will remain in place. UK, EU and third country businesses as patent holders, third parties and applicants can continue to make decisions on the basis of the current legislation. Patent examiners will continue to apply the same law when scrutinising patent applications in this area. Third parties who wish to challenge the validity of a patent will be able to do so on the same grounds as at present.

For compulsory licensing, UK, EU or third country businesses as holders of patents or plant variety rights which are valid in the UK will continue to be able to apply for a compulsory licence, where there is an overlap between the rights.

UK, EU and third country businesses will continue to be able to obtain a compulsory licence for manufacturing a patented medicine to meet a specific health need in a developing country.

For pharmaceutical product testing, UK, EU or third country businesses can continue to rely on the exceptions from patent infringement provided for various studies, trials and tests carried out on a pharmaceutical product.

Actions for businesses and other stakeholders

Any existing rights and licences in force in the UK will remain in force automatically after March 2019 and no action is required from the right or licence holder. For UK, EU and third country businesses there will be no significant change to the legal requirements or the application processes. Pending applications will continue to be assessed on the same basis, and new applications can continue to be filed.

Supplementary protection certificate holders, applicants for supplementary protection certificates, and third parties may wish to familiarise themselves with any changes to the related regulatory processes (human and veterinary medicines and chemicals). <u>All technical notices can be found here</u>.

Unitary patent and Unified Patent Court

Before 29 March 2019

The Unified Patent Court will hear cases relating to European patents and the new unitary patent – both administered by the non-EU European Patent Office. The unitary patent is a new type of patent and will be a single patent covering a number of European states.

The Unified Patent Court will be an international patent court established through an international agreement (the Unified Patent Court Agreement) between 25 EU countries. The Unified Patent Court is intended to provide businesses with a streamlined process for enforcing patents through a single court, rather than through multiple courts in multiple countries. The Unified Patent Court (UPC) is not yet in force, with the start date being dependent on ratification of the Unified Patent Court Agreement by Germany. It is unclear whether the Unified Patent Court and unitary patent will start before 29 March 2019.

After March 2019 if there's no deal

There are two different scenarios for the Unified Patent Court:

- The Unified Patent Court does not come into force. The UK has ratified the Unified Patent Court Agreement but ratification by Germany is still outstanding. If the Unified Patent Court is never fully ratified, the domestic legislation to bring it into force will never take effect in the UK. In this scenario, there will be no changes for UK and EU businesses at the point that the UK exits the EU.
- Unified Patent Court comes into force. If the Unified Patent Court is ratified and comes into force, there will be actions that UK and EU businesses, organisations and individuals may need to consider. The UK will explore whether it would be possible to remain within the Unified Patent Court and unitary patent systems in a 'no deal' scenario. In the event that the Unified Patent Court and unitary patent come into force and the UK needs to withdraw from one or both systems, please see the implications below.

Implications

If the Unified Patent Court comes into force and the UK needs to withdraw from both the Unified Patent Court and unitary patent, businesses will no longer be able to use the Unified Patent Court and unitary patent to protect their inventions within the UK. Existing unitary

patents will give rise to equivalent UK patent protection to ensure continued protection in the UK.

UK business will still be able to use the Unified Patent Court and unitary patent to protect their inventions within the contracting EU countries. However in the UK, businesses will only have the option of protecting their inventions using national patents (including patents available from the non-EU European Patent Office) and UK courts.

UK business will still be open to litigation within the Unified Patent Court based on actions they undertake within the contracting EU countries if they infringe existing rights.

EU business will no longer be able to use the Unified Patent Court and unitary patent to protect their inventions within the UK but will be able to apply for domestic UK rights as they can now, via the UK Intellectual Property Office and the non-EU European Patent Office.

Actions for businesses and other stakeholders

If the Unified Patent Court comes into force before March 2019 and the UK needs to withdraw from the Unified Patent Court and unitary patent:

- UK, EU and third country businesses will still be able to use the Unified Patent Court and unitary patent to protect their inventions within the EU
- any existing unitary patents (UPs) will give rise to patent protection within the UK with no action required by the right holder. The UP system will only come into force when the Unified Patent Court is operational. UPs will not be available to businesses until this point
- provision will be made regarding the status of any pending cases before the Unified Patent Court at exit
- UK, EU and third country businesses seeking protection in the UK for their inventions
 will need to use national patents (including patents available from the non-EU
 European Patent Office) and the UK court system

Businesses may wish to seek legal advice on how these arrangements could affect their business model or intellectual property rights. <u>Additional information is available on the Unified Patent Court website</u>.

Correspondence addresses and confidentiality for UK patents

UK withdrawal is expected to have consequences on the rights of UK businesses, organisations and representatives to represent themselves, and on their choice of representatives in relation to EU trade marks and registered Community designs. However European Patent Attorneys based in the UK will continue to be able to represent applicants before the European Patent Office. Please see the notice published by the European Patent Office.

When a business, organisation or individual (right holder) applies for a UK patent at the UK Intellectual Property Office, they must supply an address for service which is within the

European Economic Area (EEA) (which currently includes the EU and hence the UK). UK right holders generally have a UK address for service, either because they appoint a UK-based intellectual property representative to act for them and represent their interests before the Intellectual Property Office, or they represent themselves. Some EEA business, organisations or individuals may also have a UK address for service, if they have appointed a UK intellectual property representative. There are, however, some UK businesses, and many from outside the UK, who have an address for service within the EEA but outside the UK.

Legal professional privilege is given to communications between registered intellectual property representatives and their clients. This means that in legal proceedings in the UK, for example, such communications are considered confidential and will not, generally, be shared with those on the other side of the dispute. This privilege is provided for in the UK's intellectual property legislation.

Legal professional privilege is given to patent attorneys registered in the UK and to those intellectual property representatives who are not based in the UK, but are on the 'list of representatives' for the European Patent Office. This reflects the geographical area covered by the European Patent Convention (a non-EU international agreement).

After 29 March 2019 if there's no deal

There will be no immediate changes to the UK address for service rules. Privilege for patent attorneys will remain unaffected as this is not determined by reference to EU membership.

Implications

There will be no immediate implications for UK, EU or third country businesses. The current rules will remain in place at the point the UK exits the EU.

Actions for businesses and other stakeholders

There are no immediate actions for UK, EU or third country businesses. The current rules will remain in place at the point the UK exits the EU.

Further information

The government will be working closely with business representatives, trade associations and other stakeholders on the implications of our plans.

In order to prepare the UK's statute book for its exit from the EU the UK government will be passing technical changes through statutory legislation in Parliament over the coming months, using powers under the EU (Withdrawal) Act 2018. The government will be publishing detailed guidance alongside any legislative changes and will work closely with business representatives, trade associations and stakeholders on the implications.

The Intellectual Property Office has also published a <u>factsheet on intellectual property rights</u> and EU exit.

This notice is meant for guidance only. You should consider whether you need separate professional advice before making specific preparations.

It is part of the government's ongoing programme of planning for all possible outcomes. We expect to negotiate a successful deal with the EU.

The UK government is clear that in this scenario we must respect our unique relationship with Ireland, with whom we share a land border and who are co-signatories of the Belfast Agreement. The UK government has consistently placed upholding the Agreement and its successors at the heart of our approach. It enshrines the consent principle on which Northern Ireland's constitutional status rests. We recognise the basis it has provided for the deep economic and social cooperation on the island of Ireland. This includes North-South cooperation between Northern Ireland and Ireland, which we're committed to protecting in line with the letter and spirit of Strand two of the Agreement.

The Irish government have indicated they would need to discuss arrangements in the event of no deal with the European Commission and EU countries. The UK would stand ready in this scenario to engage constructively to meet our commitments and act in the best interests of the people of Northern Ireland, recognising the very significant challenges that the lack of a UK-EU legal agreement would pose in this unique and highly sensitive context.

It remains, though, the responsibility of the UK government, as the sovereign government in Northern Ireland, to continue preparations for the full range of potential outcomes, including no deal. As we do, and as decisions are made, we'll take full account of the unique circumstances of Northern Ireland.

Norway, Iceland and Liechtenstein are party to the Agreement on the European Economic Area and participate in other EU arrangements. As such, in many areas, these countries adopt EU rules. Where this is the case, these technical notices may also apply to them, and EEA businesses and citizens should consider whether they need to take any steps to prepare for a 'no deal' scenario.